REMARKS

The communication mailed June 17, 2005, has been received and reviewed. Claims 1-41 are currently pending in the application. Claim 39 is withdrawn from consideration. Claims 1-3, 7-12, 16-21, 25-31, 35-38, 40 and 41 are rejected. Claims 4-6, 13-15, 22-24 and 32-34 are objected to. Applicants have amended claims 1, 2, 4-11, 13-20, 22-30, 32-38, 40, and 41. Claims 3, 12, 21, and 31 are cancelled herein. Claims 42 and 43 have been added herein. It is respectfully submitted that no now mater has been added. Applicants respectfully request reconsideration of the application as amended herein.

Drawings

Figures 5, 7, and 8 are objected to as allegedly being illegible. Corrected drawings are required in reply to the Office Action.

The attached sheets of drawings include clarification of Figures 5, 7 and 8. Specifically, for FIG. 5, the background of the graph was improved and the vertical bars of the graph were made more distinguishable with the use of hatching. For FIG. 7, the bars of the graph were distinguished using hatching marks. For FIG. 8, the figure resolution was improved. Applicants submit that such revisions address the Examiner's objections and respectfully request reconsideration of the drawings.

Claim Rejections 35 U.S.C. § 112, Second Paragraph

Independent claims 1, 10, 19 and 29, and dependent claims 2, 3, 7-9, 11, 12, 16-18, 20, 21, 25-28, 30, 31, 35-38, 40 and 41 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are allegedly indefinite in the recitation of "a heterologous glycerol-3-phosphate dehydrogenase that is less sensitive to feedback inhibition than wild-type glycerol-3-phosphate dehydrogenase" on the basis that it is unclear what would constitute the wild-type enzyme. Applicants assert that one of skill in the art would know that "wild-type" refers to the native plant enzyme of the plant.

Applicants have cancelled claims 3, 12, 21, and 31 thus making the rejection as to these claims moot. Furthermore, to remove any alleged indefiniteness, applicants have amended independent claims 1, 10, 19 and 29 to include the element "a heterologous glycerol-3-phosphate dehydrogenase that is less sensitive to feedback inhibition than a wild-type glycerol-3-phosphate dehydrogenase **of the plant**." The amendments confirm that the wild-type enzyme refers to that of the plant and the heterologous glycerol-3-phosphate dehydrogenase (GPDH) would be less sensitive to feedback inhibition than the wild-type plant enzyme.

Therefore, the amendments remove grounds for rejection of independent claims 1, 10, 19 and 29. and independent claims 2, 7-9, 11, 16-18, 20, 25-28, 30, 35-38, 40 and 41. Applicants respectfully request reconsideration and allowance of the claims.

Claims 3, 12, 21, and 31 are allegedly indefinite in the recitation of *gpsA2*^{FR}. Applicants have cancelled claims 3, 12, 21, and 31 thus making this rejection moot.

Claims 7, 16, 25 and 35 are allegedly indefinite in the recitation oil seed-bearing plant. Applicants have amended claims 7, 16, 25, and 35 to include the elements "an oil seed-bearing plant selected from the group consisting of *Borago officinalis*, *Brassica campestris, Brassica napus, Brassica rapa, Cannabis sativa, Carthamus tinctorius, Cocos nucifera, Crambe abyssinica, Cuphea* species, *Elaeis guinensis, Elaeis oleifera, Glycine max, Gossypium hiristum, Gossypium barbadense, Gossypium herbaceum, Helianthus annus, Linum usitatissimum, Oenethera biennis, Olea europa, Oryza sativa, Ricinus communis, Sesamum indicum, Soja max, Triticum* species and *Zea mays*. Accordingly, any alleged indefiniteness of claims 7, 16, 25 and 35 has been removed.

For the foregoing reasons, applicants respectfully request reconsideration and allowance of independent claims 1, 10, 19 and 29, and dependent claims 2, 7-9, 11, 16-18, 20, 25-28, 30, 35-38, 40 and 41.

Claim Rejections 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-3, 7-12, 16-21, 25-31, 35-38, 40 and 41 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter not described in the specification in such way

as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention.

Applicants have cancelled claims 3, 12, 21, and 31 thus making the rejection as to these claims moot.

While the specification does not disclose DNA encoding every potential GPDH that would be less sensitive to feedback inhibition than the wild-type plant enzyme, applicants respectfully submit that such a disclosure is not necessary. Applicants respectfully submit that the instant disclosure, including a specific GPDH (SEQ ID NO:1) that is less sensitive to feedback inhibition in a universal plant model, along with teachings in the specification as to how to identify and test for other less sensitive GPDH, reasonably conveys to one of skill in the art that the inventor had possession of the elements of the claimed invention at the time of filing.

Possession of the claimed invention may be shown by describing the invention with all of its elements by using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention. Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572, 19 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). Accordingly, possession of the instant invention may be shown by sufficiently describing all the claim elements and does not require disclosure of DNA encoding every potential GPDH that would be less sensitive to feedback inhibition than the wild-type plant enzyme.

The specification discloses that GPDH is common to the biosynthetic pathway of **all plants**. (Specification, page 7.) The specification describes the physical, structural and functional characteristics of GPDH. Page 1 of the specification states:

> "Glycerol-3-phosphate dehydrogenase (GPDH) (EC 1.1.1.8) is an essential enzyme for both prokaryotic and eukaryotic organisms. It catalyzes the reduction of dihydroxyacetone phosphate (DHAP) to glycerol-3-phosphate (G-3-P) using NADH as a reducing equivalent. Plant cells possess at least two isoforms of GPDH, one located in the plastids and the other in the cytosol. The purification of the cytosolic GDPH from spinach has been reported. The product of the reaction catalyzed by GDPH, G-3-P, is a precursors for the synthesis of all glycerol lipid species, including membrane and storage lipids."

Furthermore, the specification describes the elements of the claimed invention with an embodiment in the plant *Arabidopsis thaliana* which is widely recognized as a laboratory model for plant genetic and biochemical studies. Id. It is well known to those of skill in the art that information concerning the genetic control of biological processes in *Arabidopsis* will be transferable to many plant species. Id. Moreover, the disclosed heterologous GDPH gene (SEQ ID NO:1) was isolated from *E. coli*, another universal laboratory bacterial model. (Specification, pages 6-7.) Those of skill in the art know that DNA sequences of *E. coli* genes are used as reference sequences to find heterologous genes in many other organisms. Therefore, one of skill in the art would be able to use the disclosed GPDH sequence (SEQ ID NO:1) as a probe for other heterologous GDPH encoding genes.

As such, disclosing a heterologous GPDH, derived from *E. coli*, that is less sensitive to feedback inhibition than the wild-type plant enzyme in *Arabidopsis thaliana*, provides a universal plant model system conveying to one of skill in the art that the inventor had possession of the claimed invention. Accordingly, if the written description is sufficient for making an embodiment of the claimed invention using *Arabidopsis thaliana*, the description is also sufficiently enabled for the use the invention in a wide variety of plant species.

More particularly, the specification discloses the specific DNA and amino acid sequences (SEQ ID NO:1 and SEQ ID NO:2) of a less sensitive GPDH and a step-by-step disclosure of molecular biological techniques including analysis of a heterologous GPDH, construction of a plant transformation vector, transformation of the desired plant species, and analysis of the feedback inhibition of the transformed plant and its fatty acid profile. (Specification, pages 9-15.) As such, the specification describes all the claim elements using multiple descriptive means, including structures, figures, diagrams and formulas that fully set forth the claimed invention and reasonably convey to one of skill in the art that the inventor had possession of the claimed invention.

For the foregoing reasons, applicants respectfully requests that the rejection under 35 U.S.C. § 112, first paragraph, written description be removed and that the claims be reconsidered and allowed.

Claim Rejections 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1-3, 7-12, 16-21, 25-31, 35-38, 40 and 41 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner stated that the specification *is enabling* for a method of using DNA encoding SEQ ID NO:2 to transform a plant. (Office Action, page 4.) However, the Examiner alleges that the specification does not provide enablement for a method of expressing in a plant any GPDH that is less sensitive to feedback inhibition than wild-type GPDH and plants transformed by that method, or use of a DNA sequence encoding GPDH having a single amino acid substitution that renders it feedback defective, while not significantly altering its catalytic ability or to $gpsA2^{FR}$. Id.

Applicants have cancelled claims 3, 12, 21, and 31 thus making the rejection as to these claims moot.

Applicants respectfully affirm that the specification is enabling for the full scope of the instant claims without undue experimentation.

To satisfy the enablement requirement, a specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997). "While every aspect of a generic claim certainly need not have been carried out by the inventor, or exemplified in the specification, reasonable detail must be provided in order to enable member of the public to understand and carry out the invention." Id. at 1366. Additionally, the specification need not teach what is well known in the art. Hybritech v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986).

Therefore, the question to ask when evaluating the satisfaction of the enablement requirement is whether one of ordinary skill in the art could make and use the invention without undue experimentation and with a reasonable expectation of success by following the description in the patent specification.

When determining undue experimentation, the PTO and the courts look to the factors outlined in In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). These factual considerations

include the quantity of experimentation necessary, the presence or absence of working examples, the nature of the invention, the state of the prior art, and the predictability or unpredictability of the art. Id.

In In re Wands, the United States Court of Appeals, Federal Circuit (CAFC) reversed the rejection for lack of enablement for an application claiming monoclonal hybridomas which secrete specific antibodies. Id. at 740. The CAFC found the disclosure of the Wands patent enabling because there was a high level of skill in the monoclonal antibody art and, despite the relative unpredictable nature of the technology, the patent disclosure provided guidance and real working examples of the invention. Id. at 738.

The CAFC recognized the complexity of the inventive technology but disagreed with the PTO, reasoning that the existing working examples, along with the specification, would allow one of ordinary skill in the art to make and use the invention. Id. at 740. The CAFC stated that a considerable amount of experimentation is permissible if it is reasonable with regards to the nature of the art or if the specification provides a reasonable amount of guidance. Id. at 737. The CAFC stated that practitioners of the monoclonal antibody art are prepared to experiment and screen numerous hybridomas to find one that makes the desired antibodies and that such experimentation is not deemed undue. Id. at 740. The CAFC reasoned that the specification contained considerable direction and guidance on how to practice the claimed invention, presented working examples, that all the methods needed to practice the invention were well known, and that there was a high level of skill in the art at the time the application was filed. Id.

Following the analysis from In re Wands, the specification of the instant invention also allows one of skill in the art to make and use the invention without undue experimentation. The specification discloses detailed laboratory protocols and guidance for the full scope of the claims, the referenced methods are well known by those of skill in the art, a working example is disclosed using a universal plant model, and the level of skill in the art was high at the time of filing.

More particularly, the specification discloses the DNA and amino acid sequence of a less sensitive heterologous GPDH encoded by an *E. coli gpsA* gene named $gpsA2^{FR}$ (SEQ ID NO:1

and SEQ ID NO:2). (Specification, page 6.) The *gpsA2*^{FR} gene contains a point mutation in the DNA sequence comprising the substitution of an A by a C at the third nucleotide of codon 255 in the *gpsA* gene (SEQ ID NO:1). Id. at 6-7. The mutation in the gene causes a change in the encoded protein (SEQ ID NO:2) comprising the substitution of Glu^{255} (GAA) with Asp^{255} (GAC).

The specification also includes a step-by-step disclosure of well known molecular biological techniques including analysis of a heterologous GPDH, construction of a plant transformation vector, transformation of the desired plant species, and analysis of the feedback inhibition of the transformed plant and its fatty acid profile. (Specification, pages 9-15.) In fact, the specification shows that *Arabidopsis thaliana* transformed with the heterologous GPDH showed changes in their fatty acid composition. Id. at 15.

Moreover, as held in In re Wands, a considerable amount of experimentation is permissible if it is reasonable with regards to the nature of the art or if the specification provides a reasonable amount of guidance. In re Wands at 737. In this case, despite any alleged unpredictability in identifying a sequence encoding a heterologous GPDH less sensitive to feedback inhibition, the inventors identified a working example and the specification provides guidance and direction for identification of other heterologous GDPH enzymes. Therefore, even if considerable experimentation is necessary, one of skill in the art is enabled to make and use the invention under detailed guidance from the specification.

Furthermore, the specification discloses a working example of the claimed invention using the plant *A. thaliana* which is widely recognized as a laboratory model for plant genetic and biochemical studies. (Specification, page 7.) It is well known to those of skill in the art that methods concerning the genetic control of biological processes in *Arabidopsis* will be transferable to many plant species. Id. Accordingly, if the written description is sufficient for making a working example of the claimed invention using *A. thaliana*, the description is also sufficient for making and using the invention for a wide variety of plant species.

Additionally, *E. coli* is another universal laboratory genetic model and those of skill in the art know that DNA sequences of *E. coli* genes may be used as reference sequences to find

heterologous genes in many other organisms. Therefore, one of skill in the art would be able to use the disclosed GPDH sequence (SEQ ID NO:1) as a probe for other heterologous GDPH encoding genes without undue experimentation.

Therefore, similar to the reasoning of the CAFC in In re Wands, applicants respectfully submit that the scope of claims 1-2, 7-11, 16-20, 25-30, 35-38, 40 and 41 is enabled, allowing one of skill in the art to make and use the scope of claims 1-2, 7-11, 16-20, 25-30, 35-38, 40 and 41 without undue experimentation. Applicants respectfully request removal of this rejection and reconsideration and allowance of claims 1-2, 7-11, 16-20, 25-30, 35-38, 40 and 41.

Claim Objections

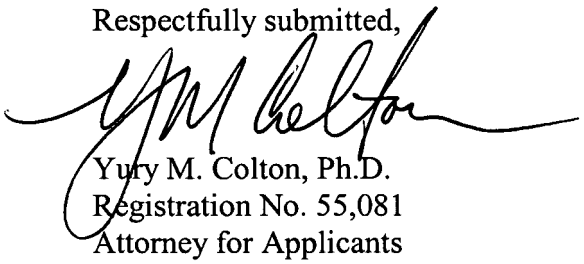
Claims 4-6, 13-15, 22-24, and 32-32 were objected to for depending on rejected base claims. For the foregoing reasons applicants submit that claims 4-6, 13-15, 22-24, and 32-32 are allowable at least by being dependent from allowable base claims. Applicants respectfully request that this objection be removed and that claims 4-6, 13-15, 22-24, and 32-32 be reconsidered and allowed.

CONCLUSION

In view of the foregoing arguments applicants respectfully submit that the rejections and objections should be withdrawn. Claims 1-2, 4-11, 13-20, 22-30, 32-38, 40 and 41 are believed to be in condition for allowance and an early notice thereof is respectfully requested.

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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IN THE DRAWINGS:

Figures 5, 7, and 8 are objected to as allegedly being illegible. The attached sheets of drawings include clarifications of to FIGS. 5, 7 and 8. Specifically, for FIG. 5, the background of the graph was improved and the vertical bars of the graph were made more distinguishable with the use of hatching. For FIG. 7, the bars of the graph were distinguished using hatching marks. For FIG. 8, the figure resolution was improved.

Additionally, formal drawings, including FIGS. 1 through 8, are provided herewith and replace the previous drawing sheets submitted for these figures. No new matter has been added.